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Dated: September 8, 2003

Signature:


(Richard Zimmermann)

Docket No.: 29715/33202B
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of:

Lewis H. LAMBERT, Jr.

Application No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Filed: **September 8, 2003**

Examiner: Not Yet Assigned

For: TREATMENT OF MYCOBACTERIAL
DISEASES BY ADMINISTRATION OF
BACTERICIDAL/PERMEABILITY-
INCREASING PROTEIN PRODUCTS

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in a prior Application No. 09/782,682 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

A concise explanation of relevance of the items listed on form PTO/SB/08 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed items

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references

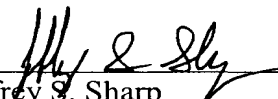
While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Respectfully submitted,

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September 8, 2003

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	Not Yet Assigned
				Filing Date	September 8, 2003
				First Named Inventor	Lewis H. Lambert, Jr.
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	4	Attorney Docket Number	29715/33202B

U.S. PATENT DOCUMENTS							
*Examiner Initials		Document Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
	A01	5,032,574	7/16/91	Wilde et al.	514	12	
	A02	5,089,274	2/18/92	Marra et al.	424	534	
	A03	5,171,739	2/15/92	Scott	514	12	
	A04	5,198,541	3/3/93	Elsbach et al.	435	69.1	
	A05	5,234,912	8/10/93	Marra et al.	514	12	
	A06	5,308,834	5/3/94	Scott et al.	514	12	
	A07	5,334,584	8/2/94	Scott et al.	514	12	
	A08	5,348,942	9/20/94	Little, II et al.	514	12	
	A09	5,763,567	6/9/98	Little	530	300	

FOREIGN PATENT DOCUMENTS								
*Examiner Initials		Document Number	Publication Date	Country	Class	Subclasses	Translation	
							Yes	No
	B01	WO 88/06038	08/25/88	WIPO				
	B02	WO 92/03535	3/5/92	WIPO				
	B03	WO 92/09621	6/11/92	WIPO				
	B04	WO 93/05797	4/4/93	WIPO				
	B05	WO 93/06228	4/1/93	WIPO				
	B06	WO 93/23434	11/25/93	WIPO				
	B07	WO 93/23540	11/25/93	WIPO				
	B08	WO 94/17819	8/18/94	WIPO				
	B09	WO 94/18323	8/18/94	WIPO				
	B10	WO 94/20128	9/15/94	WIPO				
	B11	WO 94/20129	9/15/94	WIPO				
	B12	WO 92/14155	8/20/92	WIPO				
	B13	WO 97/42966	11/20/97	WIPO				
	B14	WO 97/44056	11/27/97	WIPO				

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Sheet	2	of	4	Attorney Docket Number	29715/33202B

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)		
C01	Beaman et al., "Cytokines, Toxoplasma and Intracellular Parasitism", <i>Immun. Rev.</i> 127: 97-117 (1992)	
C02	Brown et al., "Azithromycin, Rifabutin, and Rifapentine for Treatment and Prophylaxis of Mycobacterium avium Complex in Rats Treated with Cyclosporine", <i>Antimicrob. Agents and Chemother.</i> , 37(3): 398-402 (March 1993)	
C03	Buddemeyer et al., "Automatic Quantitative Radiometric Assay of Bacterial Metabolism", <i>Clin. Chem.</i> , 22(9): 1459-1464 (1976)	
C04	Chatterjee et al., "Structural Basis of Capacity of Lipoarabinomannan to Induce Secretion of Tumor Necrosis Factor", <i>Infect. and Immun.</i> , 60(3): 1249-1253 (March 1992)	
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C08	Elsbach et al., "Separation and Purification of a Potent BPI Protein and a Closely Ass. Phospholipase A ₂ from Rabbit Polymorphonuclear Leukocytes", <i>J. Biol. Chem.</i> , 254: 11000-11009 (November 10, 1979)	
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C18	Lalande et al., "Powerful Bactericidal Activity of Sparfloxacin (AT-4140) against <i>Mycobacterium</i>	

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Sheet	3	of	4	Attorney Docket Number	29715/33202B

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)		
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	C19	Little et al., "Functional Domains of Recombinant Bactericidal/Permeability Increasing Protein (rBPI ₂₃)", <i>J. Biol. Chem.</i> , 269(3):1865-1872 (January 21, 1994)
	C20	Levy et al., "Antibacterial 15-kDa Protein Isoforms (p15s) are Members of a Novel Family of Leukocyte Proteins", <i>J. Biol. Chem.</i> , 268(8):6038-6083 (1993)
	C21	Mittal et al., "Rapid, Radiolabeled-Microculture Method That Uses Macrophages for In Vitro Evaluation of <i>Mycobacterium leprae</i> Viability and Drug Susceptibility", <i>J. Clin. Microbiol.</i> , 17(4): 704-707 (April 1983)
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	C26	Portaels et al., "Cultivable <i>Mycobacteria</i> Isolated From Organs of Armadillos Uninoculated and Inoculated with <i>Mycobacterium Leprae</i> ", <i>Ann. Inst. Pasteur/Microbiol.</i> , 136: 181-190 (1985)
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	C29	Schwab and Mandell, "The Importance of Penetration of Antimicrobial Agents into Cells", <i>Infect. Dis. Clinics of North America</i> , 3(3): 461-467 (September 1989)
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	C31	Shepard, "The Experimental Disease that Follows the Injection of Human Leprosy Bacilli into Foot-Pads of Mice", <i>J. Exp. Med.</i> , 112: 445-454 (1960)
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	C33	Shepard and McRae, "A Method for Counting Acid-fast Bacteria", <i>Int. J. Lepr.</i> , 36: 78-82 (1968)
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	C35	Sibley and Krahenbuhl, "Defective Activation of Granuloma Macrophages From

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	C37	Sibley and Krahenbuhl, " <i>Mycobacterium leprae</i> -Burdened Macrophages Are Refractory to Activation by Gamma Interferon", <i>Infect. and Immun.</i> , 55(2): 446-450 (February 1987)
	C38	Sibley et al., "Inhibition of Interferon-Gamma-Mediated Activation in Mouse Macrophages Treated With Lipoarabinomannan", <i>Clin. Exp. Immunol.</i> , 80(1): 141-148 (1990)
	C39	Sibley et al., "Intracellular Fate of <i>Mycobacterium leprae</i> in Normal Activated Mouse Macrophages", <i>Infect. and Immun.</i> , 55(3): 680-685 (March 1987)
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	C41	van den Broek, "Activity of Antibiotics against Microorganisms Ingested by Mononuclear Phagocytes", <i>Eur. J. Clin. Microbiol. Infect. Dis.</i> , 10(2): 114-118 (February 1991)
	C42	Weiss and Olsson, "Cellular and Subcellular Localization of the BPI Protein of Neutrophils", <i>Blood</i> , 69: 652-659 (February 1987)
	C43	Weiss et al., "Human BPI Protein and a Recombinant NH ₂ -Terminal Fragment Cause Killing of Serum-resistant Gram-negative Bacteria in Whole Blood and Inhibit Tumor Necrosis Factor Release Induced by the Bacteria", <i>J. Clin. Invest.</i> , 90: 1122-1130 (September 1992)
	C44	Kelly et al., "Role of Bactericidal/Permeability-Increasing Protein in the Treatment of Gram-Negative Pneumonia", <i>Surgery</i> , 144(2):140-146 (August 1993)
	C45	Edgington, "How Sweet It Is: Selectin-Mediating Drugs", <i>Bio/Technology</i> , 10:383- 386, 388, 389 (1992)

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